K123593

APR 17 2013

510(k) Summary

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter:	INOVA Diagnostics, Inc 9900 Old Grove Road, San Diego, CA, 92131
Purpose of submission:	New device(s)
Devices in the submission:	QUANTA Flash® Sm QUANTA Flash® Sm Calibrators QUANTA Flash® Sm Controls QUANTA Flash® RNP QUANTA Flash® RNP Calibrators QUANTA Flash® RNP Controls
Scientific contact:	Gabriella Lakos, Director of Research, Rheumatology INOVA Diagnostics, Inc 9900 Old Grove Road, San Diego, CA, 92131 Phone: 858-586-9900/393 Fax: 858-863-0025 email: glakos@inovadx.com
Quality Systems contact:	Tana Keivens, Director, Quality Systems INOVA Diagnostics, Inc 9900 Old Grove Road, San Diego, CA, 92131 Phone: 858-586-9900 Fax: 858-863-0025/351 email: tkeivens@inovadx.com
Preparation date:	11/19/2012
Device (1) name (assay kit):	Proprietary name: QUANTA Flash® Sm Common name: Anti-Sm Chemiluminescent Immunoassay Classification name: anti-Sm antibody, antigen and control
Regulation Description	Antinuclear antibody immunological test system
Regulation Medical Specialty	Immunology
Review Panel	Immunology
Product Code	LKP
Regulation Number	866.5100
Device Class	2
Device (1) name (Calibrators):	Proprietary name: QUANTA Flash® Sm Calibrators

	Common name:	Sm Calibrators
	Classification name:	Calibrator, secondary
Regulation Description	Calibrator	
Regulation Medical Specialty	Clinical Chemistry	
Product Code	JIT	
Regulation Number	862.1150	
Device Class	2	
Device (1) name (Controls):	Proprietary name:	QUANTA Flash® Sm Controls
	Common name:	Sm Controls
	Classification name:	Single (specified) analyte controls (assayed and unassayed)
Regulation Description	Quality control material (assayed and unassayed)	
Regulation Medical Specialty	Clinical Chemistry	
Product Code	JJX	
Regulation Number	862.1660	
Device Class	1	
Predicate device (for Device 1):	QUANTA Lite™ Sm ELISA , 510(k) number: K922831	
Device (2) name (assay kit):	Proprietary name:	QUANTA Flash® RNP
	Common name:	Anti-RNP Chemiluminescent Immunoassay
	Classification name:	anti-RNP antibody, antigen and control
Regulation Description	Antinuclear antibody immunological test system	
Regulation Medical Specialty	Immunology	
Review Panel	Immunology	
Product Code	LKO	
Regulation Number	866.5100	
Device Class	2	
Device (2) name (Calibrators):	Proprietary name:	QUANTA Flash® RNP Calibrators
	Common name:	RNP Calibrators
	Classification name:	Calibrator, secondary
Regulation Description	Calibrator	
Regulation Medical Specialty	Clinical Chemistry	

Product Code	JIT	
Regulation Number	862.1150	
Device Class	2	
Device (2) name (Controls):	Proprietary name:	QUANTA Flash® RNP Controls
	Common name:	RNP Controls
	Classification name:	single (specified) analyte controls (assayed and unassayed)
Regulation Description	Quality control material (assayed and unassayed)	
Regulation Medical Specialty	Clinical Chemistry	
Product Code	JJX	
Regulation Number	862.1660	
Device Class	1	

Predicate device (for Device2): QUANTA Lite™RNP ELISA, 510(k) number: K922833

Device (1) and (2) description:

The QUANTA Flash Sm and RNP assays are designed to run on the BIO-FLASH instrument. This platform is a fully automated closed system with continuous load and random access capabilities that automatically processes the samples, runs the assay and reports the results. It includes liquid handling hardware, luminometer and computer with software-user interface. The QUANTA Flash Sm and RNP assays utilize a reagent cartridge format, which is compatible with the BIO-FLASH instrument.

Native Sm or RNP antigen that is purified from calf thymus is coated onto paramagnetic beads. The bead suspension is lyophilized and stored in the bead tube. Prior to use in the BIO-FLASH system, the sealed reagent tubes are pierced with the reagent cartridge lid and the beads are rehydrated and resuspended using resuspension buffer by pipetting up and down with a transfer pipette. The reagent cartridge is then loaded onto the BIO-FLASH® instrument. Samples are also loaded onto the instrument in sample racks. A patient serum sample is prediluted by the BIO-FLASH with system rinse in a small disposable plastic cuvette. Small amounts of the diluted patient serum, the beads, and assay buffer are all combined into a second cuvette, and mixed. This cuvette is then incubated at 37°C. The beads are magnetized and washed several times. Isoluminol conjugated anti-human IgG antibodies are then added to the cuvette, and again incubated at 37°C. The beads are magnetized and washed repeatedly. The isoluminol conjugate is oxidized when Trigger 1 (Fe(III)coproporphyrin in sodium hydroxide solution) and Trigger 2 (urea-hydrogen peroxide in sodium chloride solution) are added to the cuvette, and the flash of light produced from this reaction is measured as Relative Light Units (RLU) by the BIO-FLASH optical system. The RLU are proportional to the amount of isoluminol conjugate that is bound to the human IgG, which is in turn proportional to the amount of anti-RNP antibodies bound to the Sm or RNP on the beads.

For quantitation, the QUANTA Flash Sm and RNP assays utilize a predefined lot specific Master Curve that is uploaded onto the instrument through the reagent cartridge barcode. Every new lot number of

reagent cartridge must be calibrated before first use with the QUANTA Flash Sm and RNP Calibrators. Based on the results obtained with the two Calibrators included in the Calibrator Set (sold separately), an instrument specific Working Curve is created, which is used to calculate chemiluminescent units (CU) from the instrument signal (RLU) obtained for each sample.

The QUANTA Flash Sm kit contains the following materials:

One (1) QUANTA Flash Sm Reagent Cartridge

One (1) vial of Resuspension buffer

One (1) Transfer pipette

The QUANTA Flash Sm reagent cartridge contains the following reagents for 50 determinations:

a. Sm antigen coated paramagnetic beads, lyophilized.
b. Assay buffer – colored pink, containing Tris-buffered saline, Tween 20, protein stabilizers and preservatives.
c. Tracer IgG – Isoluminol labeled anti-human IgG antibodies in buffer, containing protein stabilizers and preservative.

The QUANTA Flash RNP kit contains the following materials:

One (1) QUANTA Flash RNP Reagent Cartridge

One (1) vial of Resuspension buffer

One (1) Transfer pipette

The QUANTA Flash RNP reagent cartridge contains the following reagents for 50 determinations:

a. RNP antigen coated paramagnetic beads, lyophilized.
b. Assay buffer – colored pink, containing Tris-buffered saline, Tween 20, protein stabilizers and preservatives.
c. Tracer IgG – Isoluminol labeled anti-human IgG antibodies in buffer, containing protein stabilizers and preservative.

The QUANTA Flash Sm Calibrators kit and the QUANTA Flash™ RNP Calibrators kit each contain 2 vials of Calibrators:

QUANTA Flash Sm Calibrators:

- QUANTA Flash Sm Calibrator 1: Two (2) barcode labeled tubes containing 0.3 mL prediluted, ready to use reagent. Calibrators contain human antibodies to Sm in buffer, protein stabilizers, and preservatives.
- QUANTA Flash Sm Calibrator 2: Two (2) barcode labeled tubes containing 0.3 mL prediluted, ready to use reagent. Calibrators contain human antibodies to Sm in buffer, protein stabilizers, and preservatives.

QUANTA Flash RNP Calibrators:

- QUANTA Flash RNP Calibrator 1: Two (2) barcode labeled tubes containing 0.3 mL prediluted, ready to use reagent. Calibrators contain human antibodies to RNP in buffer,

protein stabilizers, and preservatives.
- QUANTA Flash RNP Calibrator 2: Two (2) barcode labeled tubes containing 0.3 mL prediluted, ready to use reagent. Calibrators contain human antibodies to RNP in buffer, protein stabilizers, and preservatives.

The QUANTA Flash Sm Controls kit and the QUANTA Flash™ RNP Controls kit each contain 2 vials of Negative Control and two vials of Positive Control:

QUANTA Flash Sm Controls:
- QUANTA Flash™ Sm Negative Control: Two (2) barcode labeled tubes containing 0.5 mL, ready to use reagent. Controls contain human antibodies to Sm in buffer, protein stabilizers, and preservatives.
- QUANTA Flash™ Sm Positive Control: Two (2) barcode labeled tubes containing 0.5 mL, ready to use reagent. Controls contain human antibodies to Sm in buffer, protein stabilizers, and preservatives.

QUANTA Flash RNP Controls:
- QUANTA Flash™ RNP Negative Control: Two (2) barcode labeled tubes containing 0.5 mL, ready to use reagent. Controls contain human antibodies to RNP in buffer, protein stabilizers, and preservatives.
- QUANTA Flash™ RNP Positive Control: Two (2) barcode labeled tubes containing 0.5 mL, ready to use reagent. Controls contain human antibodies to RNP in buffer, protein stabilizers, and preservatives.

Intended use(s):

The QUANTA Flash Sm is a chemiluminescent immunoassay for the semi-quantitative determination of IgG anti-Sm antibodies in human serum. The presence of anti-Sm antibodies, in conjunction with clinical findings and other laboratory tests, can aid in the diagnosis of Systemic Lupus Erythematosus (SLE).

The QUANTA Flash RNP is a chemiluminescent immunoassay for the semi-quantitative determination of IgG anti-ribonucleoprotein (RNP) antibodies in human serum. The presence of anti-RNP antibodies, in conjunction with clinical findings and other laboratory tests, can aid in the diagnosis of Systemic Lupus Erythematosus (SLE) and Mixed Connective Tissue Disease (MCTD).

QUANTA Flash Sm Calibrators are intended for use with the QUANTA Flash Sm chemiluminescent immunoassay for the determination of IgG anti-Sm antibodies in human serum. Each calibrator establishes a point of reference for the working curve that is used to calculate unit values.

QUANTA Flash RNP Calibrators are intended for use with the QUANTA Flash RNP chemiluminescent immunoassay for the determination of IgG anti-RNP antibodies in human serum. Each calibrator establishes a point of reference for the working curve that is used to calculate unit values.

QUANTA Flash Sm Controls are intended for use with the QUANTA Flash Sm chemiluminescent immunoassay for quality control in the determination of IgG anti-Sm antibodies in human serum.

QUANTA Flash RNP Controls are intended for use with the QUANTA Flash RNP chemiluminescent immunoassay for quality control in the determination of IgG anti-RNP antibodies in human serum.

Substantial equivalence:

The QUANTA Flash Sm, the QUANTA Flash Sm Calibrators and the QUANTA Flash Sm Controls have the same intended use and assay principle as the predicate device.
The QUANTA Flash RNP, the QUANTA Flash RNP Calibrators and the QUANTA Flash RNP Controls have the same intended use and assay principle as the predicate device.

Comparison to predicate device:

QUANTA Flash Sm reagent kit

Similarities		
Item	**QUANTA Flash Sm**	**Predicate Device**
Intended use	Semi-quantitative determination of anti-Sm antibodies in human serum	Semi-quantitative detection of anti-Sm antibodies in human serum
Assay methodology	Solid phase (heterogenous) immunoassay	Solid phase (heterogeneous) immunoassay
Traceability	International Reference Preparation is not available Results are traceable to in-house Standards	International Reference Preparation is not available
Antigen	Native Sm antigen, purified from calf thymus	Native Sm antigen, purified from calf thymus
Sample type	Serum	Serum
Shelf life	One year	One year

Differences		
Item	**QUANTA Flash Sm**	**Predicate Device**
Detection/ Operating principle	Chemiluminescent immunoassay	Enzyme-linked immunosorbent assay
Solid phase	Paramagnetic microparticles (beads)	96-well plate
Conjugate	Isoluminol conjugated anti-human IgG	HRP conjugated anti-human IgG
Calibration	Lot specific Master Curve + two Calibrators (Sold separately)	Sm ELISA Low Positive (Included in the kit)

QUANTA Flash RNP reagent kit

Similarities		
Item	**QUANTA Flash RNP**	**Predicate Device**
Intended use	Semi-quantitative determination of anti-RNP antibodies in human serum	Semi-quantitative detection of anti-RNP antibodies in human serum
Assay methodology	Solid phase (heterogenous) immunoassay	Solid phase (heterogenous) immunoassay
Traceability	International Reference Preparation is not available Results are traceable to in-house	International Reference Preparation is not available

	Standards	
Antigen	Native RNP antigen, purified from calf thymus	Native RNP antigen, purified from calf thymus
Sample type	Serum	Serum
Shelf life	One year	One year

Differences		
Item	**QUANTA Flash RNP**	**Predicate Device**
Detection/ Operating principle	Chemiluminescent immunoassay	Enzyme-linked immunosorbent assay
Solid phase	Paramagnetic microparticles (beads)	96-well plate
Conjugate	Isoluminol conjugated anti-human IgG	HRP conjugated anti-human IgG
Calibration	Lot specific Master Curve + two calibrators (Sold separately)	RNP ELISA Low Positive (Included in the kit)

QUANTA Flash Sm Calibrators

Item	**QUANTA Flash Sm Calibrators**	**Predicate Device**
Intended use	For use with the QUANTA Sm chemiluminescent immunoassay (CIA). Each calibrator establishes a point of reference for the working curve that is used to determine Chemiluminescent Unit (CU) values in the measurement of anti-Sm antibodies in human serum.	No separate intended use; calibrators are part of the kit.
Analyte	Anti-Sm antibodies	Anti-Sm antibodies
Method	QUANTA Flash Sm chemiluminescent immunoassay	QUANTA Lite Sm ELISA
Unit	CU (Chemiluminescent units) (arbitrary)	Units (arbitray)
Matrix	Human serum, buffer, stabilizers, preservative	Human serum, buffer, stabilizers, preservative
Physico-chemical characteristics	Liquid, ready to use	Liquid, ready to use
Storage	2-8 °C	2-8 °C
Shelf life	One year	One year
In-use stability	Four calibrations, maximum total 8 hours uncapped onboard the instrument.	Calibrators can be used until the end of the shelf life when stored properly

QUANTA Flash RNP Calibrators

Item	**QUANTA Flash RNP Calibrators**	**Predicate Device**

Intended use	For use with the QUANTA Flash RNP chemiluminescent immunoassay (CIA). Each calibrator establishes a point of reference for the working curve that is used to determine Chemiluminescent Unit (CU) values in the measurement of anti-RNP antibodies in serum.	No separate intended use; calibrators are part of the kit.
Analyte	Anti-RNP antibodies	Anti-RNP antibodies
Method	QUANTA Flash RNP chemiluminescent immunoassay	QUANTA Lite RNP ELISA
Matrix	Human serum, buffer, stabilizers, preservative	Human serum, buffer, stabilizers, preservative
Unit	CU (Chemiluminescent units) (arbitrary)	Units (arbitray)
Physico-chemical characteristics	Liquid, ready to use	Liquid, ready to use
Storage	2-8 °C	2-8 °C
Shelf life	One year	One year
In-use stability	Four calibrations, maximum total 8 hours uncapped onboard the instrument.	Calibrators can be used until the end of the shelf life when stored properly

QUANTA Flash Sm Controls

Item	**QUANTA Flash Sm Controls**	**Predicate Device**
Intended use	Quality control purposes of the QUANTA Flash Sm chemiluminescent immunoassay (CIA) kit.	No separate intended use; controls are part of the kit.
Analyte	Anti-Sm antibodies	Anti-Sm antibodies
Method	QUANTA Flash Sm chemiluminescent immunoassay	QUANTA Lite Sm ELISA
Unit	CU (Chemiluminescent units) (arbitrary)	Units (arbitray)
Matrix	Human serum, buffer, stabilizers, preservative	Human serum, buffer, stabilizers, preservative
Physico-chemical characteristics	Liquid, ready to use	Liquid, ready to use
Levels	2 (negative and positive)	2 (ELISA negative, high positive)
Storage	2-8 °C	2-8 °C
Shelf life	One year	One year
In-use stability	15 uses, with a maximum time of 10 minutes onboard the instrument per use, or 2 ½ hours, total.	Controls can be used until the end of the shelf life when stored properly

QUANTA Flash RNP Controls

Item	QUANTA Flash RNP Controls	Predicate Device
Intended use	Quality control purposes of the QUANTA Flash RNP chemiluminescent immunoassay (CIA) kit.	No separate intended use; controls are part of the kit.
Analyte	Anti-RNP antibodies	Anti-RNP antibodies
Method	QUANTA Flash RNP chemiluminescent immunoassay	QUANTA Lite RNP ELISA
Matrix	Human serum, buffer, stabilizers, preservative	Human serum, buffer, stabilizers, preservative
Unit	CU (Chemiluminescent units) (arbitrary)	Units (arbitray)
Physico-chemical characteristics	Liquid, ready to use	Liquid, ready to use
Levels	2 (negative and positive)	2 (ELISA negative, high positive)
Storage	2-8 °C	2-8 °C
Shelf life	One year	One year
In-use stability	15 uses, with a maximum time of 10 minutes onboard the instrument per use, or 2 ½ hours, total.	Controls can be used until the end of the shelf life when stored properly

Value assignment and traceability of Calibrators and Controls

The QUANTA Flash Sm and RNP Calibrators and Controls are manufactured by diluting human serum that contains high titer of anti-Sm or anti-RNP antibodies with a buffer containing stabilizers and preservative. The human serum is obtained from commercial sources and it is tested for markers of infectious substances.
The target CU is achieved through trial dilutions on small scale. Once a dilution is selected, the Calibrators and Control are bulked, tested, and adjusted. Upon completion of the manufacturing process, the Calibrators and Controls are tested on at least two instruments, on at least two lots of reagent cartridge, in replicates of 10 to determine final value assignment.

There are currently no recognized international standards for the measurement of anti-Sm and anti-RNP antibodies.
Calibrator and Control values are directly traceable to in-house Standards that are used to create the Master Curve for the QUANTA Flash Sm and QUANTA Flash RNP assays.

Performance characteristics

Precision

The precision of the QUANTA Flash Sm assay was evaluated on 5 samples containing various concentrations of Sm antibodies in accordance with CLSI EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Procedures - Approved Guideline: samples were run in duplicates, twice a day, for at least 20 days. Data were analyzed with the Analyse-it for Excel method evaluation software,

and within run, between run, between day and total precisions are summarized in the Table below. All %CV values were within the acceptance limit, 15%.

			Within-Run Precision (repeatability)		Between-Run		Between-Day Precision		Total Precision	
Sample ID	N	Mean (CU)	SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	80	13.1	0.9	6.5	0.2	1.5	0.7	5.6	1.1	8.7
2	80	22.0	2.1	9.7	1.0	4.6	0.9	4.2	2.5	11.5
3	84	93.0	6.0	6.4	0.5	0.5	4.8	5.2	7.7	8.3
4	88	237.7	20.6	8.7	16.8	7.1	6.4	2.7	27.3	11.5
5	84	338.6	18.1	5.3	9.9	2.9	19.7	5.8	28.5	8.4

The precision of the QUANTA Flash RNP assay was evaluated on 7 samples containing various concentrations of RNP antibodies in accordance with CLSI EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Procedures - Approved Guideline: samples were run in duplicates, twice a day, for at least 20 days. Data were analyzed with the Analyse-it for Excel method evaluation software, and within run, between run, between day and total precision are summarized in the Table below. All %CV values were within the acceptance limit, 15%.

			Within-Run Precision (repeatability)		Between-Run Precision		Between-Day Precision		Total Precision	
Sample ID	N	Mean (CU)	SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	92	6.7	0.2	3.5	0.0	0.0	0.4	5.3	0.4	6.4
2	84	24.8	0.9	3.7	0.0	0.0	0.8	3.0	1.2	4.8
3	88	31.6	1.1	3.4	0.7	2.2	2.7	8.5	3.0	9.4
4	92	120.7	4.9	4.1	4.5	3.7	4.5	3.7	8.0	6.6
5	88	218.6	9.3	4.2	7.8	3.6	20.3	9.3	23.6	10.8
6	88	319.5	12.0	3.7	14.0	4.4	11.6	3.6	21.8	6.8
7	96	409.6	19.6	4.8	18.2	4.5	23.3	5.7	35.5	8.7

Reproducibility

Three samples for Sm and RNP each were tested on two different regent lots, using two different lots of Calibrators, by two operators. Samples were run in quadruplicates, two times a day, for 10 days, to generate 80 data points. Data were analyzed with the Analyse-it for Excel method evaluation software, and within run, between reagent lots, between calibrator lots, between operators and total precision were calculated and the results are summarized in the Tables below. All %CV values were within the acceptance limit, 15%.

QUANTA Flash Sm

			Within Run		Between Reagent Lots		Between Calibrator Lots		Between Operators		Total	
Sample	Mean (CU)	Number of replicates	SD (CU)	CV (%)	SD (CU)	CV (%)	SD (CU)	CV (%)	SD (CU)	CV (%)	SD (CU)	CV (%)
Sample #1	15.2	80	0.4	2.8	1.4	9.4	1.1	6.9	1.1	6.9	1.1	7.0
Sample #2	23.3	80	0.6	2.4	2.5	10.7	1.8	7.6	1.7	7.3	1.8	7.7
Sample #3	157.3	80	5.5	3.5	15.8	10.1	15.1	9.6	13.1	8.4	13.0	8.3

QUANTA Flash RNP

			Within Run		Between Reagent Lots		Between Calibrator Lots		Between Operators		Total	
Sample	Mean (CU)	Number of replicates	SD (CU)	CV (%)	SD (CU)	CV (%)	SD (CU)	CV (%)	SD (CU)	CV (%)	SD (CU)	CV (%)
Sample #1	15.3	80	0.4	2.9	0.5	3.1	0.5	3.3	0.3	1.8	**0.4**	**2.8**
Sample #2	23.1	80	0.5	2.3	0.7	2.8	0.7	3.1	0.4	1.7	**0.6**	**2.6**
Sample #3	173.1	80	5.4	3.1	6.2	3.6	5.1	2.9	3.1	1.8	**5.1**	**2.9**

Limit of Blank, Limit of Detection

QUANTA Flash Sm:
The Limit of Detection (LoD) of the QUANTA Flash Sm assay is 803 RLU, which is below the analytical measuring range of the assay. It was determined consistent with CLSI EP17-A guideline with proportions of false positives (alpha) less than 5% and false negatives (beta) less than 5%; based on 140 determinations, with 60 measurements on blank samples and 80 measurements of low level samples. The LoB is 540 RLU. Because the curve ends at 3.3 RLU (which is equal to approximately 2430 RLU), it was not possible to calculate the LoB (540 RLU) and LoD (803 RLU) in CUs, only in RLUs (instrument signal).

QUANTA Flash RNP:
The Limit of Detection (LoD) of the QUANTA Flash RNP assay is 1128.8 RLU, which is below the analytical measuring range of the assay. It was determined consistent with CLSI EP17-A guideline with proportions

of false positives (alpha) less than 5% and false negatives (beta) less than 5%; based on 140 determinations, with 60 measurements on blank samples and 80 measurements of low level samples. The LoB is 713 RLU. Because the curve ends at 3.5 RLU (which is equal to approximately 3450 RLU), it was not possible to calculate the LoB (713 RLU) and LoD (1128.8 RLU) in CUs, only in RLUs (instrument signal).

Analytical Measuring Range

QUANTA Flash Sm:
The analytical measuring range (AMR) of the assay (determined by the lowest and highest points of the Master Curve) is 3.3 CU to 693.5 CU, which corresponds to the linear range of the assay. If a patient result is less than 3.3 CU, the BIO-FLASH system will report it as "<3.3 CU". Since this is less than 20 CU, it is considered a negative result. If a patient result is greater than 693.5 CU, the BIO-FLASH system will report it as ">693.5 CU". This is considered a positive result. The BIO-FLASH software has an Auto-Rerun option available (see description and validation in the next paragraph). If this option is selected, the instrument will automatically rerun any sample that has a result of >693.5 CU after additional 10 fold dilution, thereby bringing the measured value within the AMR.

The linearity of the AMR was evaluated by a study according to CLSI EP6-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline. Five serum samples with various Sm antibody concentrations were diluted with a low negative serum to obtain values that covered a range approximately 20% wider than the AMR. All specimens showed dilution linearity individually, and the combined data yielded the following results with linear regression:

Sample	Slope (95% CI)	Y-intercept (95% CI)	R^2
All Samples (n=5)	0.99 (0.97 to 1.00)	0.81 (-3.2 to 4.8)	0.99

QUANTA Flash RNP:
The analytical measuring range (AMR) of the assay (determined by the lowest and highest points of the Master Curve) is 3.5 CU to 643.8 CU, which corresponds to the linear range of the assay. If a patient result is less than 3.5 CU, the BIO-FLASH system will report it as "<3.5 CU". Since this is less than 20 CU, it is considered a negative result. If a patient result is greater than 643.8 CU, the BIO-FLASH system will report it as ">643.8 CU". This is considered a positive result. The BIO-FLASH software has an Auto-Rerun option available (see description and validation in the next paragraph). If this option is selected, the instrument will automatically rerun any sample that has a result of >643.8 CU after additional 10 fold dilution, thereby bringing the measured value within the AMR.

The linearity of the AMR was evaluated by a study according to CLSI EP6-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline. Five serum samples with various anti-RNP concentrations were diluted with a low negative serum to obtain values that covered a range approximately 20% wider than the AMR. All six specimens showed dilution linearity individually, and the combined data yielded the following results with linear regression:

Sample	Slope (95% CI)	Y-intercept (95% CI)	R^2
All Samples (n=5)	1.00 (1.00 to 1.02)	-5.17 (-8.27 to -2.07)	1.00

Auto-rerun function

The BIO-FLASH software has an Auto-rerun option available. If this option is selected, the instrument will automatically rerun any sample that has a result of >693.5 CU for Sm and > 643.8 CU for RNP after additional 10 fold dilution, thereby bringing the measured value within the AMR. The final result will be calculated by the software. As the highest value that can be measured is 693.5 CU for Sm and 643.8 CU for RNP, the highest value that can be reported is 6935 CU and 6438 CU, respectively.

To validate the Auto-rerun function, five (Sm) and six (RNP) high positive specimens with results above the analytical measuring range were selected for the Sm and the RNP assays, respectively. The samples were run with the Auto-rerun function enabled on the BIO-FLASH. Then the specimens were manually diluted the same way as it happens in the Auto-rerun function (10 fold dilution), and tested on the BIO-FLASH. The results were within the analytical measuring range after auto-rerun or manual dilution for all specimens. The % recovery values for results obtained with the auto-rerun results compared to the results obtained by manual dilution were between 87.6% and 97.7% for Sm (average 91.5%), and between 82.5% and 102.2% for RNP (average 96.3%), respectively (within the ± 20% acceptance limit).

Interference

QUANTA Flash Sm:
The interference study was performed according to CLSI EP07-A2, Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition. Three specimens were tested (negative: 16.3 CU; around the cutoff weak positive: 28.6 CU; high positive: 190.7 CU). Interfering substances were spiked into every specimen at three different concentrations in 10% of total specimen volume, and the resulting samples were assessed in triplicates with the Sm assay. Recovery of the unit values was calculated compared to control samples spiked with the same volume of diluents. Acceptance criteria for the interference studies were 85% - 115% recovery, or ± 4 CU difference, whichever is greater.

No interference was detected with bilirubin up to 10 mg/dL (recovery: 103% to 108% or within ± 4 CU), hemoglobin up to 200 mg/dL (recovery: 97% to 108% or within ± 4 CU), triglycerides up to 1000 mg/dL (recovery: 105% to 111% or within ± 4 CU), cholesterol up to 224.3 mg/dL (recovery: 105% to 111% or within ± 4 CU), and RF IgM up to 500 IU/mL (recovery: 85% to 95% or within ± 4 CU).

QUANTA Flash RNP:
The interference study was performed according to CLSI EP07-A2, Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition. Three specimens were tested (negative: 8.8 CU; weak positive: 55.5 CU; high positive: 280.3). Interfering substances were spiked into every specimen at three different concentrations in 10% of total specimen volume, and the resulting samples were assessed in triplicates with the RNP assay. Recovery of the unit values was calculated compared to control samples spiked with the same volume of diluents. Acceptance criteria for the interference studies were 85% - 115% recovery, or ± 4 CU difference, whichever is greater.

No interference was detected with bilirubin up to 10 mg/dL (recovery: 96% to 112%), hemoglobin up to 200 mg/dL (recovery: 88% to 108%), triglycerides up to 1000 mg/dL (recovery: 86% to 109%), cholesterol up to 224.3 mg/dL (recovery: 86% to 109%), and RF IgM up to 500 IU/mL (recovery: 88% to 113%).

High concentration hook effect

To assess hook effect, the measurement signal (relative light units, RLU) was examined for the samples that were used to validate the Auto-rerun function (five Sm and six RNP high positive specimens), before and after automatic or manual dilution. All sera produced significantly higher RLU values (above the AMR) when used "as is" compared to the manually or automatically diluted ones, thereby confirming that high positive specimens above the analytical measuring range do not show hook effect up to 2429 CU in the Sm assay and up to 3140 CU in the RNP assay (the highest concentrations tested).

Cross-reactivity

QUANTA Flash Sm:

To test potential cross-reactivity with autoantibodies and infection-induced antibodies, 233 patient samples with various antibodies to autoimmune or infectious disease markers were tested. Three samples from patients with scleroderma, one sample with HIV antibodies, and one sample with MCTD/primary biliary cirrhosis (PBC) overlap were positive on the QUANTA Flash Sm. All other serum samples were negative:

Patient Group	N	Positive	Percent Positive
Autoimmune liver disease	2	0	0%
Viral hepatitis	19	0	0%
Scleroderma	74	3	4.1%
Sjögren's Syndrome	5	0	0%
Rheumatoid arthritis	70	0	0%
Systemic rheumatic disease, other	53	1	1.9%
Infectious disease (HIV + syphilis)	10	1	10%
Total	**233**	**5**	**2.1%**

QUANTA Flash RNP:

To test potential cross-reactivity with autoantibodies and infection-induced antibodies, 246 patient samples were tested from patients with infectious diseases, autoimmune diseases and connective tissue diseases. Eight samples from patients with scleroderma, two samples from patients with RA, one sample from a patient with PM/DM, and one sample with HIV antibodies were positive on the QUANTA Flash RNP. As anti-RNP antibodies can sometimes be detected in patients with systemic sclerosis, and as all of these scleroderma samples were positive on the predicate RNP ELISA, too, it is highly possible that those samples are true positives, and not cross-reacting samples. All other serum samples were negative:

Patient Group	N	Positive	Percent Positive
Autoimmune liver disease	2	0	0%
Viral hepatitis	20	0	0%
Scleroderma	76	8	10.5%
Sjögren's Syndrome	6	0	0%
Rheumatoid arthritis	70	2	2.9%

Systemic rheumatic disease, other	48	0	0%
Poly- and Dermatomyositis	14	1	7.1
Infectious disease (HIV + syphilis)	10	1	10%
Total	**246**	**12**	**4.9%**

Stability

Shelf life

To establish the initial claim for shelf life, accelerated stability studies were performed.

Accelerated stability testing was performed on each of the following sealed components in the QUANTA Flash Sm and RNP to establish initial stability claim: the beads, the two calibrators, and the negative and positive controls. Each week a new sealed component was placed in the incubator, and all components were tested at the end of the experiment together with the one that was stored at 5º ± 3°C. The recovery of the measured values was calculated for each time point (compared to those obtained with 5º ± 3°C stored reagent). All calculations were performed by comparing results of sealed components stored at 5º ± 3°C (control) to those stored at 37° ± 3°C (test) for 1, 2, 3, and 4 weeks, where one week is equal to six months at 5º ± 3°C. Linear regression analysis was performed between recovery values and the number of days in those cases when at least 3 data points were available at each time point; otherwise, individual data points were analyzed.

Acceptance criteria for one year preliminary expiration dating were:

- Controls and Calibrators:
a) if regression analysis is used, the lower 95% CI interval of the regression line is ≥ 90% at 2 weeks, and no individual data point has ≤ 80% recovery,
b) If individual data points are analyzed, recovery values are > 90% at day 14.
- Microparticles:
with regression analysis, the lower 95% CI interval of the regression line is ≥ 85% at 2 weeks, and no individual data point has ≤ 75% recovery.

Sm beads, RNP beads, Sm Calibrators, RNP Calibrators, Sm Controls and RNP Controls each fulfilled the acceptance criteria above, so one year expiration dating was assigned to each component.

In-use (onboard) stability

Sm Calibrators

During assessing on-board stability, Calibrators were placed, uncapped, onboard the instrument, and calibration was performed altogether five times, then a panel of characterized patient specimens were run on each calibration curve.

Acceptance criteria were: Calibrators are considered stable if all five calibrations performed in the 8.5 hour period are successful, and Calibrator RLU recovery values are between 90% and 110% compared to the first use.

A total of 5 successful calibrations were performed over an 8.5 hour period. Calibrator RLU values remained within the 90-110% range. Moreover, all patient panel samples ran within their expected range. This supports the claim that calibrators can be used for up to 4 calibrations over an 8 hour period.

Sm Controls

During assessing on-board stability, Controls were assayed twice each day over 10 days, for a total of 20 runs. The controls were left uncapped, onboard the instrument for 15 minutes per run. When not in use, the controls were capped, and stored at 2-8°C.

Acceptance criteria: Controls are considered stable when all replicates run within their established range, moreover, and the linear regression line obtained by plotting %recovery values against the number of runs stays between 85% and 115% at day run 15.

Both controls ran within their respective acceptable range for all 20 runs, resulting in a %CV of 5.9% for the Negative Control and 4.8% for the Positive Control. These results support the claim that controls can be used for 15 times, up to 2.5 hours total.

Sm Reagent Cartridge

To determine the in-use stability of the QUANTA Flash Sm reagent pack, three lots of cartridges were tested by using five serum specimens (with different reactivity levels). The specimens were tested periodically up to 48 days, twice a day. Recoveries were calculated compared to the day zero average values, and linear regression analysis was performed. The claim was established using the following criteria (using the one that is fulfilled first):

a)The stability claim is established at the day where the lower 95% confidence interval of the regression line reaches 85% recovery, or
b) When 2% or more of the recovery data is ≤ 75%.

The onboard stability results of the three lots are the following:
RP0005: 33 days
RP0006: 40 days
121005: 39 days

Using these criteria, the in-use (onboard) stability of the Sm reagent cartridge was set at 33 days.

RNP Calibrators

During assessing on-board stability, Calibrators were placed, uncapped, onboard the instrument, and calibration was performed altogether five times, then a panel of characterized patient specimens were run on each calibration curve.

Acceptance criteria were: Calibrators are considered stable if all five calibrations performed in the 8.5 hour period are successful, and Calibrator RLU recovery values are between 90% and 110% compared to the first use.

A total of 5 successful calibrations were performed over an 8.5 hour period. Calibrator RLU values remained within the 90-110% range. Moreover, all patient panel samples ran within their expected range. This supports the claim that calibrators can be used for up to 4 calibrations over an 8 hour period.

RNP Controls

During assessing on-board stability, Controls were assayed twice each day over 10 days, for a total of 20 runs. The controls were left uncapped, onboard the instrument for 15 minutes per run. When not in use, the controls were capped, and stored at 2-8°C.

Acceptance criteria: Controls are considered stable when all replicates run within their established range, moreover, and the linear regression line obtained by plotting %recovery values against the number of runs stays between 85% and 115% at day run 15.

Both controls ran within their respective acceptable range for all 20 runs, resulting in a %CV of 5.9% for the Negative Control and 6.9% for the Positive Control. These results support the claim that controls can be used for 15 times, up to 2.5 hours total.

RNP Reagent Cartridge

To determine the in-use stability of the QUANTA Flash RNP reagent pack, three lots of cartridges were tested by using four to eight serum specimens (with different reactivity levels). The specimens were tested periodically up to 41 days, twice a day. Recoveries were calculated compared to the day zero average values, and linear regression analysis was performed. The claim was established using the following criteria (using the one that is fulfilled first):

a)The stability claim is established at the day where the lower 95% confidence interval of the regression line reaches 85% recovery, or
b) When 2% or more of the recovery data is ≤ 75%.

The onboard stability results of the three lots are the following:
111001: 28 days
121002: 28 days
121003: 31 days

Using these criteria, the in-use (onboard) stability of the RNP reagent cartridge was set at 28 days.

The Stability Claims are tabulated below for easy review. The 1 year shelf life begins from the date of manufacture.

Sm stability claims

Product	Unopened shelf life	After being opened
QUANTA Flash Sm Reagent Cartridge	Until the expiration date on the label (currently 1 year).	33 days (onboard only – cannot be resealed).

Sm Calibrator 1 and 2	Until the expiration date on the label (currently 1 year).	4 uses, up to 8 hours onboard total
Sm Negative Control and Positive Control	Until the expiration date on the label (currently 1 year).	15 uses, up to 2.5 hours onboard total

RNP stability claims

Product	Unopened shelf life	After being opened
QUANTA Flash RNP Reagent Cartridge	Until the expiration date on the label (currently 1 year).	28 days (onboard only – cannot be resealed).
RNP Calibrator 1 and 2	Until the expiration date on the label (currently 1 year).	4 uses, up to 8 hours onboard total
RNP Negative Control and Positive Control	Until the expiration date on the label (currently 1 year).	15 uses, up to 2.5 hours onboard total

Cut-off, reference range

QUANTA Flash Sm:	Negative	<20 CU
	Positive	≥20 CU
QUANTA Flash RNP :	Negative	<20 CU
	Positive	≥20 CU

QUANTA Flash Sm:
The reference population for establishing the reference interval for the Sm assay consisted of 232 subjects:

Apparently healthy blood donors	129
Non-autoimmune thyroid disease	41
Autoimmune thyroid disease	42
Samples for patients with infectious diseases	20

All specimens were the same matrix (serum) as specified in the Intended Use. All specimens were unaltered. The cut off was established in accordance to CLSI C28-A3c: Defining, Establishing, and

Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline - Third Edition. The Analyse-it for Excel software was used to make the calculations. The distribution of the results was non-normal (Saphiro-Wilk $p<0.0001$), so the non-parametric percentile method was used. The cut-off was established at the 99th percentile of the results obtained on the reference subjects, and was assigned a value of 20 CU.

QUANTA Flash RNP:
The reference population for establishing the reference interval for the RNP assay consisted of 255 subjects:

Apparently healthy blood donors	127
Non-autoimmune thyroid disease	41
Autoimmune thyroid disease	42
Samples for patients with infectious diseases	20
Rheumatoid arthritis	25

All specimens were the same matrix (serum) as specified in the Intended Use. All specimens were unaltered. The cut off was established in accordance to CLSI C28-A3c: Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline - Third Edition. The Analyse-it for Excel software was used to make the calculations. The distribution of the results was non-normal (Saphiro-Wilk $p<0.0001$), so the non-parametric percentile method was used. The cut-off was established at 99th percentile of the results obtained on the reference subjects, and was assigned a value of 20 CU.

Clinical sensitivity, specificity

QUANTA Flash Sm:

A separate set of samples, none of which were used in establishing the reference range, was used to validate the clinical performance of the Sm CIA.
A total of 379 samples were included in the clinical sensitivity, specificity calculations for the QUANTA Flash Sm. This cohort includes:

- 63 samples from SLE patients from Neuss Center for Rheumatology, Neuss, Germany
- 83 samples from SLE patients from Dr. Carlos von Mühlen, Germany
- 74 samples from systemic sclerosis patients
- 70 samples from rheumatoid arthritis patients
- 5 samples from Sjogren's syndrome patients
- 53 samples from patients with other systemic rheumatic diseases
- 2 samples from patients with autoimmune liver disease
- 19 samples from patients with viral hepatitis
- 10 samples from patients with other infectious diseases(5 HIV, 5 syphilis)

All samples were run on the QUANTA Flash Sm CIA. The results were analyzed to calculate sensitivity and specificity for SLE. Results obtained on proficiency testing specimens were excluded from the clinical sensitivity/specificity calculations.

Clinical Analysis N=379		Diagnosis			Analysis (95% confidence)
		SLE	Not SLE	Total	
QUANTA Flash Sm	Positive	21	5	26	Sensitivity = 14.4% (9.1-21.1%)
	Negative	125	228	353	Specificity = 97.9% (95.1-99.3%)
	Total	146	233	379	

To assess diagnostic efficiency, ROC analysis was performed on the validation sample pool for SLE (excluding apparently healthy blood donors). The results are below:

Test	Area	95% CI		SE	Z	p
QUANTA Flash Sm	0.62	0.57	to 0.67	0.025	4.81	<0.0001

QUANTA Flash RNP:

A separate set of samples, none of which were used in establishing the reference range, was used to validate the clinical performance of the RNP CIA.
A total of 424 samples were included in the Validation Set for the QUANTA Flash RNP. This Validation Set includes:

- 62 samples from SLE patients from Neuss Center for Rheumatology, Neuss, Germany
- 32 samples from MCTD patients from Neuss Center for Rheumatology, Neuss, Germany
- 84 samples from SLE patients from Dr. Carlos von Mühlen, Germany
- 48 samples from patients with other systemic rheumatic diseases (not SLE and not MCTD)
- 2 patients with autoimmune liver disease
- 6 patients with Sjögren's syndrome
- 76 samples from patients with systemic sclerosis
- 70 samples from rheumatoid arthritis patients
- 14 samples from patients with polymyositis/dermatomyositis
- 20 samples from patients with viral hepatitis
- 10 samples from patients with other infectious diseases(5 HIV, 5 syphilis)

All samples were run on the QUANTA Flash RNP CIA. The results were analyzed to calculate sensitivity and specificity for SLE and MCTD separately, as well as combined.

Clinical sensitivity and specificity of the QUANTA Flash RNP in MCTD+SLE:

Clinical Analysis N=424		Diagnosis			Analysis (95% confidence)
		SLE/MCTD	Control	Total	
QUANTA Flash™ RNP	Positive	66	12	78	Sensitivity = 37.1% (30.0%-44.6%)
	Negative	112	234	346	Specificity = 95.1% (91.6%-97.5%)
	Total	178	246	424	

Clinical sensitivity and specificity of the QUANTA Flash RNP in SLE:

Clinical Analysis N=392		Diagnosis			Analysis (95% confidence)
		SLE	Controls	Total	
QUANTA Flash RNP	Positive	42	12	54	Sensitivity = 28.8% (21.6-36.8%)
	Negative	104	234	338	Specificity = 95.1% (91.6-97.5%)
	Total	146	246	392	

Clinical sensitivity and specificity of the QUANTA Flash RNP in MCTD:

Clinical Analysis N=278		Diagnosis			Analysis (95% confidence)
		MCTD	Controls	Total	
QUANTA Flash RNP	Positive	24	12	36	Sensitivity = 75.0% (56.6-88.5%)
	Negative	8	234	242	Specificity = 95.1% (91.6-97.5%)
	Total	32	246	278	

To assess diagnostic efficiency, ROC analysis was performed on the validation sample pool for SLE. The results are below:

Test	Area	95% CI		SE	Z	p
QUANTA Flash RNP	0.61	0.55	to 0.67	0.030	3.57	0.0002

To assess diagnostic efficiency, ROC analysis was performed on the validation sample pool for MCTD. The results are below:

Test	Area	95% CI		SE	Z	p
QUANTA Flash RNP	0.87	0.79	to 0.95	0.041	8.95	<0.0001

Expected values

Sm

The expected value in the normal population is "negative". Anti-Sm autoantibody levels were analyzed

on a panel of 101 apparently healthy blood donors (71 females and 30 males, ages 18 to 55 years, with an average and median age of 34 years) using the QUANTA Flash Sm. With the cut-off of 20 CU, 1 (1.0 %) of the samples was positive on the QUANTA Flash Sm. The mean concentration was 3.6 CU, and the values ranged from <3.3 to 20.5 CU.

RNP

The expected value in the normal population is "negative". Anti-RNP autoantibody levels were analyzed using the QUANTA Flash RNP on a panel of 101 apparently healthy blood donors (71 females/30 males, ages 18 to 55 years, with an average and median age of 34 years). With a cut-off of 20 CU, one (1%) of the samples was positive on the QUANTA Flash RNP. The mean concentration was 5.7 CU, and the values ranged from <3.5 to 196.8 CU.

Comparison with predicate device

QUANTA Flash Sm:

Samples for the method comparison analysis included samples from the clinical validation studies (SLE patients and disease controls), as well as samples from proficiency surveys (CAP and NEQAS) and samples from apparently healthy blood donors with results within the AMR of the assay. These samples were tested on both the QUANTA Flash Sm and on the predicate ELISA.

Method Comparison (N=119)		Sm ELISA			Percent Agreement (95% Confidence)
		Positive	Negative	Total	
QUANTA Flash Sm CIA	Positive	35	6	41	Pos. Agreement = 92.1% (78.6 - 98.3%)
	Negative	3	75	78	Neg. Agreement = 92.6% (84.6 - 97.2%)
	Total	38	81	119	Total Agreement = 92.4% (86.1 - 96.5%)

QUANTA Flash RNP:

Samples for the method comparison analysis included samples from the clinical validation studies (SLE, MCTD patients and disease controls), as well as samples from apparently healthy blood donors with results within the AMR of the assay. These samples were tested on both the QUANTA Flash RNP and on the predicate ELISA.

Method Comparison (N=167)		RNP ELISA			Percent Agreement (95% Confidence)
		Positive	Negative	Total	
QUANTA Flash RNP CIA	Positive	46	6	52	Pos. Agreement = 80.7% (68.1 - 90.0%)
	Negative	11	104	115	Neg. Agreement = 94.5% (88.5 - 98.0%)
	Total	57	110	167	Total Agreement = 89.8% (84.2 - 94.0%)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 17, 2013

INOVA DIAGNOSTICS, INC.
c/o GABRIELLA LAKOS, Ph.D.
DIRECTOR, RHEUMATOLOGY RESEARCH
9900 OLD GROVE ROAD
SAN DIEGO CA 92131

Re: K123593
Trade/Device Name: QUANTA Flash® Sm
QUANTA Flash® Sm Calibrators
QUANTA Flash® Sm Controls
QUANTA Flash® RNP
QUANTA Flash® RNP Calibrators
QUANTA Flash® RNP Controls
Regulation Number: 21 CFR 866.5100
Regulation Name: Antinuclear antibody immunological test system
Regulatory Class: II
Product Code: LKP, LKO, JIT, JJX
Dated: April 15, 2013
Received: April 16, 2013

Dear Dr. Lakos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements

as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan -S

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k123593

Device Name: QUANTA Flash® Sm

Indications for Use:

The QUANTA Flash Sm is a chemiluminescent immunoassay for the semi-quantitative determination of IgG anti-Sm antibodies in human serum. The presence of anti-Sm antibodies, in conjunction with clinical findings and other laboratory tests, can aid in the diagnosis of Systemic Lupus Erythematosus (SLE).

Prescription Use ___X___	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Maria M. Chan -S

Division Sign-Off

Office of In Vitro Diagnostics and Radiological Health

510(k) k123593

Indications for Use Form

510(k) Number (if known): k123593

Device Name: QUANTA Flash® Sm Calibrators

Indications for Use:

QUANTA Flash Sm Calibrators are intended for use with the QUANTA Flash Sm chemiluminescent immunoassay for the determination of IgG anti-Sm antibodies in human serum. Each calibrator establishes a point of reference for the working curve that is used to calculate unit values.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Maria M. Chan -S

Division Sign-Off

Office of In Vitro Diagnostics and Radiological Health

510(k) k123593

Indications for Use Form

510(k) Number (if known): k123593

Device Name: QUANTA Flash® Sm Controls

Indications for Use:

QUANTA Flash Sm Controls are intended for use with the QUANTA Flash Sm chemiluminescent immunoassay for quality control in the determination of IgG anti-Sm antibodies in human serum.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Maria M. Chan -S

Division Sign-Off

Office of In Vitro Diagnostics and Radiological Health

510(k) k123593

Indications for Use Form

510(k) Number (if known): k123593

Device Name: QUANTA Flash® RNP

Indications for Use:

The QUANTA Flash RNP is a chemiluminescent immunoassay for the semi-quantitative determination of IgG anti-ribonucleoprotein (RNP) antibodies in human serum. The presence of anti-RNP antibodies, in conjunction with clinical findings and other laboratory tests, can aid in the diagnosis of Systemic Lupus Erythematosus (SLE) and Mixed Connective Tissue Disease (MCTD).

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Maria M. Chan -S

Division Sign-Off

Office of In Vitro Diagnostics and Radiological Health

510(k) k123593

Indications for Use Form

510(k) Number (if known): k123593

Device Name: QUANTA Flash® RNP Calibrators

Indications for Use:

QUANTA Flash RNP Calibrators are intended for use with the QUANTA Flash RNP chemiluminescent immunoassay for the determination of IgG anti-RNP antibodies in human serum. Each calibrator establishes a point of reference for the working curve that is used to calculate unit values.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Maria M. Chan -S

Division Sign-Off

Office of In Vitro Diagnostics and Radiological Health

510(k) k123593

Indications for Use Form

510(k) Number (if known): k123593

Device Name: QUANTA Flash® RNP Controls

Indications for Use:

QUANTA Flash RNP Controls are intended for use with the QUANTA Flash RNP chemiluminescent immunoassay for quality control in the determination of IgG anti-RNP antibodies in human serum.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Maria M. Chan -S

Division Sign-Off

Office of In Vitro Diagnostics and Radiological Health

510(k) k123593